



UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/173,463 10/14/98 BLACK M 240052.429

000500 HM12/0615
SEED INTELLECTUAL PROPERTY LAW GROUP PLL
701 FIFTH AVE
SUITE 6300
SEATTLE WA 98104-7092

EXAMINER

FRONDA, C	
ART UNIT	PAPER NUMBER

1652
DATE MAILED: 06/15/01

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/173,463

Applicant(s)

Black

Examiner
Christian L. Fronda

Group Art Unit
1652



☒ Responsive to communication(s) filed on November 29, 2000 (paper no. 14)

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-15 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-15 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1652

DETAILED ACTION

1. In the AMENDMENT dated November 29, 2000 (paper no.14) Applicant has amended claims 2 and 12.
2. Claims 1-15 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-11 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Munir et al. in view of Graham et al., Kit et al., Drake et al., Waldman et al., Munch-Petersen et al., Balasubramaniam et al., Brown et al., and Donarian et al. The teachings of each of the references have been stated in the previous Office Action.

Applicant's arguments filed November 29, 2000 (paper no. 14) have been fully considered but they are not persuasive. Applicant argues that claims 1-11 are neither taught nor suggested by the teachings of Munir or any of the secondary references in combination with the teachings of Munir.

As stated in the previous Office Action, Balasubramaniam et al. and Brown et al. teach that the Q substrate binding domain and the DRH binding domain are important in nucleoside binding and that in order to obtain mutants having the desired properties (i.e. increased enzyme activity or greater substrate/analog/prodrug specificity) this region must be modified. One of ordinary skill in the art would have used the random mutagenesis method taught by Munir et al. to randomly mutate the codons encoding these important domains in order to obtain and screen for mutants with enhanced properties such as greater substrate, analog, or prodrug specificity and that such mutants having increased activity toward prodrugs such as ganciclovir are expected to be more effective in the treatment of cancer when these mutants are used in gene therapy as taught by Donarian et al. Accordingly, claims 1-11 stand rejected.

Art Unit: 1652

4. Claims 12-15 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Esandi et al. in view of Munir et al., Graham et al., Kit et al., and Donarian et al. The teachings of each of the references have been stated in the previous Office Action.

Applicant's arguments filed November 29, 2000 (paper no. 14) have been fully considered but they are not persuasive. Applicant argues that claims 12-15 are neither taught nor suggested by the teachings of Esandi et al. or any of the secondary references in combination with the teachings of Esandi et al.

As stated in the previous Office Action, Esandi et al. teach a vector containing the cytomegalovirus immediate early promoter and the herpes simplex thymidine kinase gene; gene therapy of experimental malignant mesothelioma using this vector; and potential use of this gene therapy as a local treatment for malignant mesothelioma; and Donarian et al. further teach that the α fetoprotein promoter (a tissue specific promoter) is suitable in the control of prodrug activating or toxic enzymes in the gene therapy of cancer.

As stated in the previous Office Action, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make an expression vector comprising a promoter operably linked to the claimed nucleic acid encoding the claimed *Herpesviridae* thymidine kinase by inserting the mutated DNA encoding mutant thymidine kinase described above in the rejection of claims 1-11 into the expression vector taught by Esandi et al. in order to express thymidine kinase mutants in cancer cells of specific tissue origin which is expected to be effective in the treatment of cancer when these mutants are used in gene therapy as taught by Donarian et al. Accordingly, claims 1-11 stand rejected.

Conclusion

#. No claim is allowed.


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1652

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF



PONNATHAPUACHU •
SUPERVISORY PATENT
TECHNOLOGY CENTER 1600